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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/694,586	10/27/2003	Ekambar R. Kandimalla	HYB-005US5	3762

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EXAMINER	
HORNING, MICHELLE S	
ART UNIT	PAPER NUMBER
1648	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/16/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/694,586	KANDIMALLA ET AL.	
	Examiner	Art Unit	
	Michelle Horning	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 January 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *10/27/2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

OFFICE ACTION

This office action is responsive to communication filed 1/23/2007. The status of the claims is as follows: claims 1-19 and 23-38 are canceled and claims 20-22 are under current examination.

Claim Rejections

35 U.S.C. 112, 2nd paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 20-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 21 and 22 depend on the invention of claim 20. Claim 20 is drawn to an oligonucleotide that comprises a dinucleotide, 5'-Py-Pu-3', a 3' -3' linkage and one or two accessible 5'ends. Further, this oligonucleotide is not complementary to either the *gag* or *tat* gene of HIV-1. Because the oligonucleotide includes a 3' –3' linker, it is not clear how such an oligonucleotide can be complementary to a gene of HIV-1. Further clarification is required.

35 U.S.C. 103(a)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 20-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chaix et al (1996) and US Patent 6028183 (filed 1997, hereinafter as "Lin"). The limitations of the rejected claims are as follows: an immunostimulatory oligonucleotide compound comprising an immunostimulatory dinucleotide of formula 5'-Py-Pu-3', a 3' –3' linkage, and one or two accessible 5' ends; provided that the oligonucleotide is not complementary to the *gag* or *tat* gene of HIV-1; wherein the olgionucleotide comprises two accessible 5' ends and wherein the immunostimulatory dinucleotide comprises a non-natural pyrimidine nucleoside.

Chaix et al discloses oligonucleotide sequences that include a 3' –3' linker and two accessible 5' ends (see sequences 2 and 4 in Table 1). Further, these sequences comprise an immunostimulatory dinucleotide of formula 5'-Py-Pu-3'. Chaix et al discloses a marked increase in the stability of these sequences (see Conclusion). Chaix et al teaches using sequences that *are* complementary to either the *gag* or *tat* gene of HIV-1. It would have been obvious to one of ordinary skill in the art to modify the

compounds taught by Chaix et al and use 3' –3' linkers in oligonucleotides other than those that are complementary to either the *tat* or *gag* gene of HIV-1. One would have been motivated to do so, as taught by Chaix et al (see last paragraph), in order to increase the oligonucleotides' stability against nuclease-mediated degradation in contrast to 5' –3' oligonucleotides. There would have been a reasonable expectation of success given that the underlying techniques are well described in the prior art. Thus, the invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Chaix et al does not disclose using a non-natural pyrimidine. Lin teaches using oligonucleotides containing pyrimidine derivatives (see Title and Abstract). This entire document describes modifications and synthesis of such modifications that would lead to an enhancement of nuclease stability (see paragraph 159). Of note, page 12 of the instant application states the following: "A base is considered to be non-natural if it is not select from the group consisting of thymine, guanine, cytosine, adenine and uracil". It would have been obvious to one of ordinary skill in the art to modify the compounds taught by Lin and further incorporate a non-natural nucleoside. One would have been motivated to do do, as taught by Lin, in order to "improve the therapeutic efficacy of oligonucleotides" (see column 1, Objects of Invention). There would have been a reasonable expectation of success given the underlying methods and their effects are well taught in the prior art. Thus, the invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 20-21 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 11/174448. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to an oligonucleotide comprising a linker and two accessible 5' ends.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 20-21 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 11/234074. Although the conflicting claims are not

identical, they are not patentably distinct from each other because both sets of claims are drawn to an oligonucleotide comprising a linker and two accessible 5' ends.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 20-21 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 11/234075. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to an oligonucleotide comprising a linker and two accessible 5' ends.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 20-22 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 11/174002. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to an oligonucleotide comprising a linker, a non-natural pyrimidine and two accessible 5' ends.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 20-21 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 11/173983. Although the conflicting claims are not

identical, they are not patentably distinct from each other because both sets of claims are drawn to an oligonucleotide comprising a linker and two accessible 5' ends.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 20-21 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 11/173794. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to an oligonucleotide comprising a linker and two accessible 5' ends.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 20-21 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 11/174282. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to an oligonucleotide comprising a linker and two accessible 5' ends.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 20-21 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 11/173938. Although the conflicting claims are not

identical, they are not patentably distinct from each other because both sets of claims are drawn to an oligonucleotide comprising a linker and two accessible 5' ends.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 20-21 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 11/174450. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to an oligonucleotide comprising a linker and two accessible 5' ends.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 20-21 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 39-40 of copending Application No. 11/270805. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to an oligonucleotide comprising a linker and two accessible 5' ends.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 20-21 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 11/174448. Although the conflicting claims are not

identical, they are not patentably distinct from each other because both sets of claims are drawn to an oligonucleotide comprising a linker and two accessible 5' ends.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 20-21 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2 and 7 of copending Application No. 11/757345. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to an oligonucleotide comprising a linker and two accessible 5' ends.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 20-22 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 6, 7, 10 and 24 of copending Application No. 10/279684. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to an oligonucleotide comprising a linker and two accessible 5' ends.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

CONCLUSION

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michelle Horning whose telephone number is 571-272-9036. The examiner can normally be reached on Monday-Friday, 8:30 am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 570-272-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for unpublished application is available through Private PAIR only. For more information about PAIR system, see htt://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Patent Examiner

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